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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,411	09/12/2005	Habib Zaghouni	07316.0002.PCUS00	8513
24573 7590 10/30/2008 BELL, BOYD & LLOYD, LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER EWOLDT, GERALD R	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 10/30/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,411	Applicant(s) ZAGHOUBANI ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-65 is/are pending in the application.
- 4a) Of the above claim(s) 49, 50 and 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 48 and 51-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/1/08 and 8/7/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendments, remarks, and IDS, filed 8/05/08, are acknowledged.

Claims 49, 50, and 62-65 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 47, 48, and 51-61 are under examination.

2. The substitute Title and Abstract have been entered.

3. In view of Applicant's amendment the previous rejection under the second paragraph of 35 U.S.C. 112 has been withdrawn.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 47, 48, and 51-61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/30706 (IDS) in view of Liu et al. (2000).

As set forth previously, WO 98/30706 teaches an engineered fusion protein for the treatment of IDDM, in particular, a humanized IgG_{2b} chimeric protein wherein an autoantigen peptide is inserted into the D segment of a CDR3 loop, further including a soluble pharmaceutical composition of the construct (see particularly Figure 1, page 13, and Example II).

The reference teaching differs from the claimed invention only in that it does not teach Ig-chimera constructs comprising the GAD peptides of SEQ ID NOS:3 and 4.

Liu et al. teaches that the peptides of SEQ ID NOS:3 and 4 comprise known T cell epitopes (see particularly page 14597, column 1 paragraph). The reference also teaches that the epitopes are thought to be involved in the diabetogenic process (see particularly page 14596, paragraph spanning columns 1 and 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce the construct of WO 98/30706 employing the T cell epitopes of SEQ ID NOS:3 and 4, as taught by Liu et al. One

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of ordinary skill in the art at the time the invention was made would have been motivated to use the epitopes of Liu et al. because they were thought to be involved in the diabetogenic process and thus, suitable for use in the constructs of the instant claims.

Applicant's arguments, filed 8/05/08, have been fully considered but are not found persuasive. Applicant argues a lack of articulated rationale for the rejection and a lack of expectation of success.

Regarding rationale, the primary reference, WO 98/30706 (Applicant's own work), makes clear that the generic Ig construct (of which the instant claims encompass a subgenus and species for the treatment of diabetes) has a broad range of applicability for the treatment of autoimmune disorders, allergic responses, and transplant rejection (page 19), indeed, the constructs are particularly applicable to for the treatment of any T cell-mediated autoimmune disorders including insulin-dependent diabetes (page 10). All that is required is that an appropriate T cell agonist be chosen and inserted into the construct. The secondary reference, Liu et al. teaches that the peptides of SEQ ID NOS:3 and 4 are "immunodominant peptides" involved in the development of type 1 (insulin-dependent) diabetes (page 14569). Accordingly, the combined references render obvious the Ig constructs of the instant claims. Regarding a lack of expectation of success, it is unclear why Applicant makes this argument given that the Inventor himself teaches the functionality of the entire genus of immune-suppressing Ig constructs in the primary reference.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Eileen O'Hara can be reached on (571) 272-0878.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/G.R. Ewoldt/
G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600